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LUCAS MEYER, INC.  
P.O. BOX 3218  
DECATUR · IL 62524



TEL: (800) SOY-3660  
TEL: (217) 875-3660  
FAX (217) 877-5046

January 8, 1997

Office of Special Nutritionals (HFS-450)  
Center for Food Safety and Applied Nutrition  
Food and Drug Administration  
200 C St., SW  
Washington, D.C. 20204

Re: Section 403(r)(6) Notification for Leci-PC®

Dear Sir or Madam:

I am writing to provide notice, in accordance with section 403(r)(6) of the Federal Food, Drug, and Cosmetic Act and proposed 21 C.F.R. § 101.93, of the statements of nutritional support made by Lucas Meyer, Inc. for its Leci-PC® dietary supplement product.

#### **Name of Dietary Supplement and Dietary Ingredient**

Leci-PC® contains the dietary ingredient PhosphatidylCholine (PC), a naturally occurring phospholipid. Labeling for Leci-PC® contains the following statements of nutritional support regarding PC:

#### **Text of Statements Made**

- ◆ PC is an extremely versatile cell nutrient and a building block for cell membranes. All cells in the body depend heavily on their membrane systems and therefore rely heavily on PC for their entire range of activities.
- ◆ Clinical studies show that dietary PC helps maintain the essential functions of liver cells, and assists the liver in recovery from toxic attack.
- ◆ Supplementation with PC can help restore the liver's needed metabolic efficiency.
- ◆ Dietary PhosphatidylCholine, such as Leci-PC®, is effectively absorbed, provides a ready source of PC and helps increase the levels of PC needed for membrane health. Dietary PC is also an effective nutritional source of choline.

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♦ PC plays an essential role in the processes that maintain metabolic efficiency within the cell and contribute to cell stability (homeostasis). Dietary PC helps maintain the levels of PC needed for optimum cell function, in the liver as well as in all the body's other organs.

**Address of Lucas Meyer, Inc.**

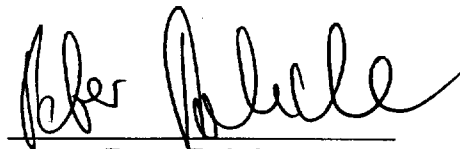
The address for Lucas Meyer, Inc. is:

Lucas Meyer, Inc.  
P.O. Box 3218  
Decatur IL 62524

**Certification**

I certify in my role as President of Lucas Meyer, Inc. that all of the information contained in this notice is complete and accurate, and that Lucas Meyer, Inc. has substantiation that each statement of nutritional support listed in the notice is truthful and not misleading.

Respectfully submitted,

A handwritten signature in black ink, appearing to read "Peter Rohde", written over a horizontal line.

Peter Rohde  
President & CEO  
Lucas Meyer, Inc.